



General

Guideline Title

Recommendations in primary care for the most efficacious and cost effective pharmacologic treatment for *Helicobacter pylori* in non-pregnant adults.

Bibliographic Source(s)

University of Texas at Austin, School of Nursing Family Nurse Practitioner Program. Recommendations in primary care for the most efficacious and cost effective pharmacologic treatment for *Helicobacter pylori* in non-pregnant adults. Austin (TX): University of Texas at Austin, School of Nursing; 2013 May. 17 p. [38 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [May 12, 2016 – Fluoroquinolone Antibacterial Drugs](#) : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Strength of recommendations (A, B, C, D, I) and quality of evidence (High, Moderate, Low) are defined at the end of the "Major Recommendations" field.

First Line Therapy

Standard Triple Therapy

(Generic proton pump inhibitor [PPI] twice a day [BID] + clarithromycin 500 mg BID + amoxicillin 1 gm BID) x 14 days

| | |
|-------|---|
| Cost: | \$165 (medication purchased individually) |
| | \$550 (Prevpac) |

OR

Bismuth Quadruple Therapy

(Generic PPI BID + tetracycline 500 mg four times a day [QID] + metronidazole 500 mg three times a day [TID] + bismuth subsalicylate 300 mg QID) x 14 days

| | |
|-------|--|
| Cost: | \$95 (medication purchased individually) |
| | \$860 (Helidac + PPI BID x 14 days) |

Standard triple therapy is recommended for patients that are not allergic to penicillin and who have not received a macrolide. If a practitioner is aware of clarithromycin resistance rates of greater than 20%, then bismuth quadruple therapy should be prescribed instead.

(Karatapanis et al., 2011; Ang et al., 2013; Duck et al., 2004; Fuccio et al., 2007; Prasertpetmanee, Mahachai, & Vilaichone, 2013; Haydee & Flores, 2010; Yoon et al., 2009; Liou et al., 2010; Luther et al., 2010)

(Grade A, High Evidence)

Second Line Therapy After Initial Treatment Failure

Levofloxacin/Amoxicillin Combination Therapy

(Generic PPI BID + amoxicillin 1 gm BID + levofloxacin 500 mg once a day [QD]) X 10 days

Cost: \$24

OR

Bismuth Quadruple Therapy

(Generic PPI BID + tetracycline 500 mg QID + metronidazole 500 mg TID + bismuth subsalicylate 300 mg QID) x 14 days

| | |
|-------|--|
| Cost: | \$95 (medication purchased individually) |
| | \$860 (Helidac + PPI BID x 14 days) |

Bismuth quadruple therapy should not be used as a second line therapy if it was used as the initial therapy.

(Gisbert, 2008; Gisbert et al., "Second-line," 2008; Gisbert et al., "Empirical rescue," 2008; Jodlowski, Lam, & Ashby, 2008; Lee et al., 2010; Li et al., 2010; Kuo et al., 2009; Kuo et al., 2013; Rokkas et al., 2009; Salazar et al., 2012; Schrauwen, Janssen, & de Boer, 2009)

(Grade A, High Evidence)

Initial Treatment in Penicillin Allergic Patient

Metronidazole/Clarithromycin Combination Therapy

(Generic PPI BID + clarithromycin 500 mg BID + metronidazole 500 mg BID) x 14 days

Cost: \$181

OR

Bismuth Quadruple Therapy

(Generic PPI BID + tetracycline 500 mg QID + metronidazole 500 mg TID + bismuth subsalicylate 300 mg QID) x 14 days

| | |
|-------|--|
| Cost: | \$95 (medication purchased individually) |
| | \$860 (Helidac + PPI BID x 14 days) |

(Talebi Beznin Abadi et al., 2012; Duck et al., 2004; Gisbert et al., 2010; Larsen et al., 2013; Salazar et al., 2012)

(Grade A, Moderate Evidence)

Second Line Therapy After Initial Treatment Failure in Penicillin Allergic Patient

Levofloxacin/Clarithromycin Combination Therapy

(Generic PPI BID + levofloxacin 500 mg BID + clarithromycin 500 mg BID) x 10 days

Cost: \$124

(Gisbert et al., 2010)

(Grade A, Low Evidence)

Treatment After Second Line Therapy Failure

Refer to gastrointestinal (GI) specialist.

Adjunct Treatment

Supplementation of standard triple therapy with *Saccharomyces boulardii* may be considered because it could increase eradication rates and decrease side effects of treatment (O'Connor et al., 2011; Song et al., 2010; Szajewska, Horvath, & Piwowarczyk, 2010). (Grade A, Moderate Evidence)

Adjunct treatment with certain prebiotics and probiotics can show favorable results in reducing adverse effects according to the Maastricht IV Conference. (Grade A, Moderate Evidence)

Failure rates of eradicating *Helicobacter pylori* are largely due to antibiotic resistance and adverse side effects. Probiotic supplementation can have a preventative effect on antibiotic-associated diarrhea and may increase eradication rates (Videlock & Cremonini, 2012; Boyanova & Mitov, 2012).

Definitions:

Quality of Evidence (Based on U.S. Preventive Services Task Force [USPSTF] Ratings)

High: There is a high level of certainty regarding the benefit based on well designed and conducted studies in primary care populations. They assess the effects of services on health outcomes. Future studies are unlikely to change this conclusion.

Moderate: The evidence available is sufficient to determine the services on health outcomes, but are limited by various factors in the studies such as size, quality or generalizability, or coherence. As more studies are produced, this could strengthen or weaken the conclusion of the evidence now available.

Low: The available evidence is insufficient to assess the effects on health outcomes. Evidence may be lacking due to study size, design, methods utilized, inconsistency or gaps in findings, lack of generalizability and lack of information on important health outcomes. More information may allow for a more accurate estimation of health outcomes.

Grading of Recommendations (Based on the USPSTF Ratings)

A. There is high certainty that the benefits are substantial. This service should be offered or provided.

B. This service is recommended. There is high certainty that there is moderate benefit and moderate certainty that there is substantial benefit. This service should be offered or provided.

C. This service is not recommended routinely by the USPSTF. Individual considerations may support providing this service. There is moderate certainty that the benefit is small. Only offer or provide this service to a specific individual if there are other reasons that support providing this service.

D. The USPSTF recommends against this service. This service should be discouraged.

I. Current evidence is insufficient to determine the risks or benefits of this service. This may be due to lack of evidence, poor quality or conflicting evidence. Clinical considerations of the USPSTF should be reviewed prior to this service being offered. Patients should understand the uncertainty about the potential risks and benefits.

Clinical Algorithm(s)

An algorithm titled "Algorithm for Efficacious & Cost-effective Pharmacologic Treatment" is provided in the appendix of the original guideline document.

Scope

Disease/Condition(s)

Helicobacter pylori infection associated with the following conditions:

- Peptic ulcer disease (PUD)
- Recurrence of ulcer
- Atrophic gastritis
- Gastric cancer
- Unexplainable iron deficiency anemia
- Vitamin B-12 deficiency
- Idiopathic thrombocytopenia (ITP)

Guideline Category

Treatment

Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Intended Users

Advanced Practice Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

To assist primary care providers with current evidenced-based practice guidelines in reference to the most efficacious and cost effective treatment for *Helicobacter pylori* in non-pregnant adults in primary care

Target Population

Non-pregnant adult population ages ≥ 18 years of age in the United States

Interventions and Practices Considered

1. Standard triple therapy: proton pump inhibitor (PPI) + clarithromycin + amoxicillin
2. Bismuth quadruple therapy: PPI + tetracycline + metronidazole + bismuth subsalicylate
3. Levofloxacin/amoxicillin combination therapy: PPI + amoxicillin + levofloxacin
4. Metronidazole/clarithromycin combination therapy: PPI + clarithromycin + metronidazole
5. Levofloxacin/clarithromycin combination therapy: PPI + levofloxacin + clarithromycin
6. Prebiotics and probiotics

Major Outcomes Considered

- Eradication of *Helicobacter pylori*
- Healing of peptic ulcer disease (PUD)
- Decreased bleeding recurrence
- Prevention or healing of atrophic gastritis
- Decreased the incidence of gastric cancer
- Improved hemoglobin levels in unexplainable iron deficiency anemia
- Improved vitamin B-12 deficiency
- Improved platelet count in idiopathic thrombocytopenic purpura (ITP) patients

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Online searches were performed for the time period January 2007 to March 2013 in the following databases: CINAHL, Cochrane, PubMed, EBSCO, Medline, and Up-To-Date.

Key words included:

- *Helicobacter pylori* (*H. pylori*)
- Treatment
- Management
- Medication
- Allergy
- Adjunctive treatment

Position statements from the American Gastroenterological Association, the American College of Gastroenterology, and the Centers for Disease Control and Prevention were also reviewed. Additional resources were identified by reviewing bibliographies of relevant articles and published guidelines.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence (Based on U.S. Preventive Services Task Force [USPSTF] Ratings)

High: There is a high level of certainty regarding the benefit based on well designed and conducted studies in primary care populations. They assess the effects of services on health outcomes. Future studies are unlikely to change this conclusion.

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Low: The available evidence is insufficient to assess the effects on health outcomes. Evidence may be lacking due to study size, design, methods utilized, inconsistency or gaps in findings, lack of generalizability and lack of information on important health outcomes. More information may allow for a more accurate estimation of health outcomes.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Journal articles were analyzed for quality based on type of study design, method, number of subjects, representative sample, generalizability of results, and applicability for target populations.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations (Based on the U.S. Preventive Services Task Force [USPSTF] Ratings)

A. There is high certainty that the benefits are substantial. This service should be offered or provided.

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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Family nurse practitioner (FNP) students developed the guideline and submitted it to the University of Texas FNP program faculty for review. Revisions were made and submitted to external expert sources. Final revisions were made based on reviewer recommendations prior to submitting to the guideline committee.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Ang TL, Wang L, Ang D, Chiam P, Fock KM, Teo EK. Is there still a role for empiric first-line triple therapy using proton pump inhibitor, amoxicillin and clarithromycin for *Helicobacter pylori* infection in Singapore? Results of a time trend analysis. *J Dig Dis*. 2013 Feb;14(2):100-4. [PubMed](#)

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment for *Helicobacter pylori* infection in the non-pregnant adult population

Potential Harms

Adverse effects of medications

Contraindications

Contraindications

- Pregnancy or breastfeeding
- Hypersensitivity to drug/class/component of amoxicillin, bismuth subsalicylate, clarithromycin, levofloxacin, metronidazole, tetracycline, *Saccharomyces boulardii*, omeprazole or other proton pump inhibitors (PPIs)
- Amoxicillin contraindications: hypersensitivity to penicillins, cephalosporins, imipenem; concomitant live bacterial vaccines
- Bismuth subsalicylate contraindications: hypersensitivity to bismuth, aspirin, or other salicylates, infectious diarrhea, high fever, von Willebrand disease, hemorrhage, ulcer or gastrointestinal (GI) bleeding with black or bloody stool, hemophilia
- Clarithromycin contraindications:
 - Co-administration with pimozide, cisapride, ergotamine, and dihydroergotamine
 - History of cholestatic jaundice/hepatic dysfunction associated with prior use of clarithromycin
 - Clarithromycin/ranitidine bismuth citrate contraindicated in severe renal impairment (creatinine clearance [CrCl] <25 mL/min)
 - History of acute porphyria
- *S. boulardii*:
 - Antifungals can reduce the effectiveness of *S. boulardii*.
 - Known allergy to *Saccharomyces cerevisiae*, severely immunocompromised, and those with indwelling vascular catheters

Qualifying Statements

Qualifying Statements

- This guideline represents the view of the University of Texas School of Nursing (SON) Family Nurse Program (FNP) students and faculty, and was arrived at after careful consideration of the evidence available and cost of pharmacologic treatments. Healthcare professionals are expected to take this guideline into account with their own clinical judgment. These guidelines do not supersede the individual responsibility of the healthcare provider to make decisions appropriate to the circumstance and to the individual patient.
- The recommendations in this guideline simplify clinical decision making and may not be appropriate in all circumstances. Patients with previous *Helicobacter pylori* treatment failures, history of gastric cancer, long term proton pump inhibitor (PPI) use, long term non-steroidal anti-inflammatory drug (NSAID) use, who are pregnant, and children younger than 18 years may require different treatment strategies not discussed in this guideline.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

University of Texas at Austin, School of Nursing Family Nurse Practitioner Program. Recommendations in primary care for the most efficacious and cost effective pharmacologic treatment for *Helicobacter pylori* in non-pregnant adults. Austin (TX): University of Texas at Austin, School of Nursing; 2013 May. 17 p. [38 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 May

Guideline Developer(s)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

Source(s) of Funding

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program

Guideline Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

No relationship exists between the guideline developers and any for-profit or non-for-profit companies or organizations that could potentially influence the guideline development.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Request from fsonstein@mail.nur.utexas.edu

Print copies: Available from the University of Texas at Austin, School of Nursing, 1700 Red River, Austin, Texas, 78701-1499. Attn: Nurse Practitioner Program

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 23, 2013. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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